DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

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Food and Drug Administration

[Docket No. 02N–0036]

Aventis Pharmaceuticals et al.; Withdrawal of Approval of 12 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 12 new drug applications (NDAs). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective ***[insert date 30 days after date of publication in the*** **Federal Register].**

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

NDA No.	Drug	Applicant
8-102	Tace (chlorotrianisene).	Aventis Pharmaceuticals, 399 Interpace, Pkwy., P.O. Box 663, Parsippany, NJ 07054.
9-925	Dyclone (dyclonine hydrochloride (HCl)) Topical Solution, 0.5% and 1%.	AstraZeneca LP, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355.
11444	Tace (chlorotrianisene) Capsules, 25 milligrams (mg).	Aventis Pharmaceuticals
14-322	Meprobamate Tablets, 200 mg and 400 mg.	IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
16-235	Tace (chlorotrianisene) Capsules, 72 mg.	Aventis Pharmaceuticals
17-829	Diprosone (betamethasone dipropionate) Aerosol.	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
19-188	Gastrocrom (cromolyn sodium) Capsules.	Celltech Pharmaceuticals, Inc., 755 Jefferson Rd.. P.O. Box 31710, Rochester, NY 14603-1710.
19-399	Total Parenteral Nutrition Electrolytes.	Abbott Laboratories, D-389 Bldg. AP30. 200 Abbott Park Rd., Abbott Park, IL 60064-3537.
20-227	Normiflo (ardeparin sodium) Injection.	Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199.
50-370	Ilotycin Gluceptate (erythromycin gluceptate).	Eli Lilly and Co., Lilly Corp. Center, Indianapolis, IN 46285.

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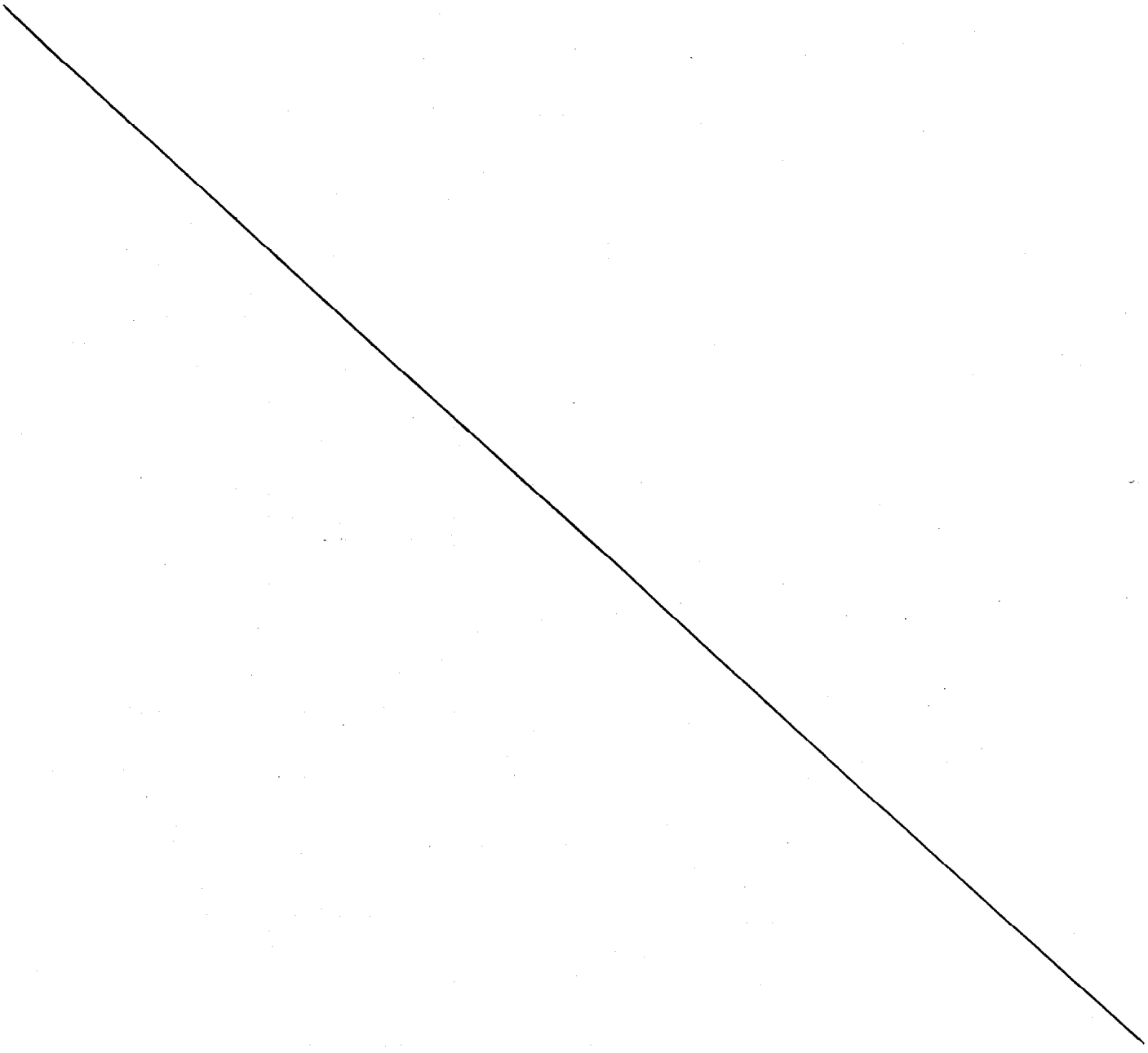
NDA No.	Drug	Applicant
50-579	Monocid (cefonicid sodium) Injection.	SmithKline Beecham Pharmaceuticals, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101-7929.
50–581	Mefoxin (cefoxitin sodium) Premixed IV Solution.	Merck & Co., Inc., P.O. Box 4, BLA-20, West Point, PA 19486.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments



and supplements thereto, is hereby withdrawn, effective ***[insert date 30 days after date of publication in the*** **Federal Register].**

Dated: 1/18/02

January 18, 2002.

Steven K. Galson,
Deputy Director,
Center for Drug Evaluation and Research.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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